REMARKS

Applicants respectfully request reconsideration and reexamination of the present application in light of the amendments and the remarks below.

Claims 1-7 are pending in this application. Claims 1-3 and 5-7 have been amended. These claim amendments are made to clarify the subject matter therein. Therefore, these amendments are submitted in order to place the claims in condition for allowance, and do not disclaim any subject matter to which the Applicants are entitled.

Rejection Under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 1-7 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention (Paper No. 20040914, pages 2-3). Applicants respectfully traverse this rejection.

The Examiner stated that claims 1-5 are directed to a method for identifying cancer cells and method claims are defined by active method steps that set forth the manner in which the method is to be performed. Claim 1 has been amended to recite the steps of the method. Support for the claim amendments may be found, for example, on pages 7, 9 and the Examples (pages 10-13) of the specification.

The Examiner stated that in claim 2, there is no antecedent basis for "the automatic information processing." Claim 2 has been amended accordingly.

The Examiner stated that in claim 3, there is no antecedent basis for "the molecular markers." Claim 1 has been amended to recite "molecular markers."

The Examiner stated that in claim 3, it is unclear as to what the phrase "with secondary colors" is modifying. Claim 3 has been amended accordingly.

The Examiner stated that in claim 6, it is unclear what the term "it" is referring to and it is unclear what "reflex testing" means because neither the claims nor the specification provide any guidance as to what Applicants intend by "reflex testing." Claim 6 has been amended to clarify the term "it." With respect to "reflex testing," a description of reflex testing may be found on page 8, lines 24-31 of the specification.

The Examiner stated that claim 7 recites a kit "containing all the necessary reagents." The claim has been amended as suggested by the Examiner.

It is thus submitted that the claims 1-7 meet the requirements of 35 USC § 112, second paragraph, and reconsideration and withdrawal of the present rejection is respectfully requested.

Rejection Under 35 U.S.C. § 102

The Examiner rejected claims 1, 2, and 5 under 35 U.S.C. § 102(b) as being anticipated by Rao, et al., (Cancer Epidemiol. Biomarkers Prev.) (Paper No. 20040914, pages 4-5). Applicants respectfully traverse this rejection.

In order to support anticipation under 35 U.S.C. §102, each and every element of a claimed invention must be disclosed within a single prior art reference. *See In re Bond*, 15 USPQ2d 1896 (Fed. Cir. 1991).

As amended, the claims recite an automatable method for identifying cancer cells and their precursors comprising the steps of contacting a cell sample or tissue sample with color marked reagents that specifically bind to the molecular markers, simultaneously detecting signal intensities of color mixtures resulting from the markers, and combining and accrediting the signal intensities.

Rao, et al., do not teach the steps of simultaneously detecting signal intensities of color mixtures resulting from the markers, and combining and accrediting the signal intensities.

Since Rao, et al., does not teach each and every limitation of the claimed invention, a proper rejection under 35 U.S.C. § 102(b) has not been established. Accordingly, Applicants respectfully request reconsideration and withdrawal of the of the present rejection.

The Examiner rejected claims 1, 3, 4, and 5 under 35 U.S.C. § 102(b) as being anticipated by McNamara, et al., (U.S. Patent No. 6,007,996) (Paper No. 20040914, pages 5-6). Applicants respectfully traverse this rejection.

As mentioned above, the claims recite an automatable method for identifying cancer cells and their precursors including the steps of simultaneously detecting signal intensities of color mixtures resulting from the markers, and combining and accrediting the signal intensities.

McNamara, et al., do not teach the steps of simultaneously detecting signal intensities of color mixtures resulting from the markers, and combining and accrediting the signal intensities.

Since McNamara,, et al., does not teach each and every limitation of the claimed invention, a proper rejection under 35 U.S.C. § 102(b) has not been established. Accordingly, Applicants respectfully request reconsideration and withdrawal of the of the present rejection.

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected claim 7 under 35 U.S.C. § 103(a) as unpatentable over either Rao, et al., or McNamara, et al., in view of U.S. Patent No. 5,109,429 (Bacus, et al.) (Paper No. 20040914, pages 6-7). Applicants respectfully traverse.

As mentioned above, the claims recite an automatable method for identifying cancer cells and their precursors including the steps of simultaneously detecting signal intensities of color mixtures resulting from the markers, and combining and accrediting the signal intensities; and test kit for implementing the method.

Neither Rao, et al., nor McNamara,, et al., teach or suggest the steps of simultaneously detecting signal intensities of color mixtures resulting from the markers, and combining and accrediting the signal intensities.

The deficiencies of Rao, et al., and McNamara,, et al., are not remedied by Bacus, et al. Bacus, et al., describes a kit, but does not describe a test kit that could be utilized to implement the claimed method. That is, Bacus, et al., do not teach the steps of simultaneously detecting signal intensities of color mixtures resulting from the markers, and combining and accrediting the signal intensities.

Since the combination of references does not teach every element of the claimed invention, these references cannot be combined to support a rejection of the claims under U.S.C. § 103(a). MPEP § 2143.

It is therefore submitted respectfully that Rao, et al., and McNamara,, et al., either singly or in combination with Bacus, et al., fails to teach or suggest the method as presently claimed, and that the current invention is novel and nonobvious in view of the prior art references.

For the foregoing reasons in this section, Applicants respectfully request reconsideration and withdrawal of the present rejections.

Double Patenting

The Examiner has rejected claims 1, 2, and 4-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6, 9, and 10 of co-pending Patent Application Serial No. 10/022,618 (Paper No. 20040914, pages 3-4).

It remains unknown what subject matter claimed and disclosed in the present application will be deemed allowable; hence any statement regarding this rejection made on Applicants' part would be premature. Therefore, Applicants respectfully traverse this rejection, and request that this rejection should be held in abeyance until subject matter is deemed allowable in this application.

CONCLUSION

For the foregoing reasons, Applicants submit that the claims are in condition for allowance and Applicants respectfully request reexamination of the present application, reconsideration and withdrawal of the present rejections, and entry of the amendments. Should there be any further matter requiring consideration, Examiner Cross is invited to contact the undersigned counsel.

If there are any further fees due in connection with the filing of the present reply, please charge the fees to undersigned's Deposit Account No. 13-3372. If a fee is required for an extension of time not accounted for, such an extension is requested and the fee should also be charged to undersigned's deposit account.

Respectfully submitted,

Susan M. Pellegrino

Susan M. Pellegrino
Reg. No. 48,972

Date: March 10, 2005

Bayer Pharmaceuticals Corporation
400 Morgan Lane
West Haven, CT 06516-4175
Telephone: (203) 812-6450
Facsimile: (203) 812-6459